

Message

From: Nalubola, Ritu [Ritu.Nalubola@fda.hhs.gov]
Sent: 3/30/2017 1:43:24 PM
To: Wozniak, Chris [wozniak.chris@epa.gov]; Penalva-Arana, Carolina [Penalva-Arana.Carolina@epa.gov]; Hoffman, Neil E - APHIS [Neil.E.Hoffman@aphis.usda.gov]; Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]; Milewski, Elizabeth [Milewski.Elizabeth@epa.gov]; Segal, Mark [Segal.Mark@epa.gov]; Sid Abel [Sidney.W.Abel@aphis.usda.gov]
Subject: RE: NASEM Report - Future of Biotechnology Compiled ERRATA comments

Thanks, Chris!

Carolina -- I believe there are no more pending items for FDA. If I missed any, please let me know.

Thx!
Ritu

From: Wozniak, Chris [mailto:wozniak.chris@epa.gov]
Sent: Thursday, March 30, 2017 9:26 AM
To: Nalubola, Ritu; Penalva-Arana, Carolina; Hoffman, Neil E - APHIS; Mendelsohn, Mike; Milewski, Elizabeth; Segal, Mark; Sid Abel
Subject: RE: NASEM Report - Future of Biotechnology Compiled ERRATA comments

Ritu,

I dropped the comment on GE sterile mosquitoes (Oxitec) since they do list 'sterile insects'. I think the listing as sterile insects does not differentiate between irradiated insects used for SIT vs true biotech or rDNA based approaches, but also figured that whoever was reading the report on future products of biotech would likely think biotech rather than the broader idea of sterility from irradiation or Wolbachia even.

Chris

From: Nalubola, Ritu [mailto:Ritu.Nalubola@fda.hhs.gov]
Sent: Thursday, March 30, 2017 6:06 AM
To: Penalva-Arana, Carolina <Penalva-Arana.Carolina@epa.gov>; Wozniak, Chris <wozniak.chris@epa.gov>; Hoffman, Neil E - APHIS <Neil.E.Hoffman@aphis.usda.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>; Segal, Mark <Segal.Mark@epa.gov>; Sid Abel <Sidney.W.Abel@aphis.usda.gov>
Subject: RE: NASEM Report - Future of Biotechnology Compiled ERRATA comments

Hi Carolina -- To circle back on the BRAG item -- the way Chris worded it seems to cover it sufficiently so we're fine with just keeping that piece as it is.
I'll stay tuned to hear from Chris or Elizabeth on the Oxitec item in case anything further is needed from my side.
Thanks much!
Ritu

From: Penalva-Arana, Carolina [mailto:Penalva-Arana.Carolina@epa.gov]
Sent: Wednesday, March 29, 2017 12:58 PM
To: Nalubola, Ritu; Wozniak, Chris; Hoffman, Neil E - APHIS; Mendelsohn, Mike; Milewski, Elizabeth; Segal, Mark; Sid Abel
Subject: Re: NASEM Report - Future of Biotechnology Compiled ERRATA comments

Here is the latest copy.

I cleaned up the minor errors and accepted corrections from Ritu and Neil.

Chris or Elizabeth, can one of you look it over and tell me if there is anything you want revised? Right now I have left the Oxytec mosquito comment even though Ritu is correct that sterile insects are included in the table and could cover Oxytec mosquitos.

Ex. 5 - Deliberative Process

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If you guys can look it over one last time, and Ritu can let me know about BRAG, I will send it to Bryan as soon as I hear from everyone.

All the best.
Carolina

From: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>

Sent: Wednesday, March 29, 2017 10:19:24 AM

To: Wozniak, Chris; Hoffman, Neil E - APHIS; Penalva-Arana, Carolina; Mendelsohn, Mike; Milewski, Elizabeth; Segal, Mark; Sid Abel

Subject: RE: NASEM Report - Future of Biotechnology Compiled ERRATA comments

Hi Chris – Thanks for flagging the last comment re: BRAG and risk assessments – I’m checking internally and will get back on this later tonight/tomorrow.

Thanks!

Ritu

From: Wozniak, Chris [<mailto:wozniak.chris@epa.gov>]

Sent: Wednesday, March 29, 2017 9:08 AM

To: Hoffman, Neil E - APHIS; Nalubola, Ritu; Penalva-Arana, Carolina; Mendelsohn, Mike; Milewski, Elizabeth; Segal, Mark; Sid Abel

Subject: RE: NASEM Report - Future of Biotechnology Compiled ERRATA comments

Attached are some suggested edits from EPA-OPP. Please note the last sentence on the page indicating impact from BRAG on EPA risk assessments; if APHIS or FDA feel the same, the sentence can be altered to include other agencies.

Thanks
Chris

From: Hoffman, Neil E - APHIS [<mailto:Neil.E.Hoffman@aphis.usda.gov>]

Sent: Wednesday, March 29, 2017 8:14 AM

To: 'Nalubola, Ritu' <Ritu.Nalubola@fda.hhs.gov>; Penalva-Arana, Carolina <Penalva-Arana.Carolina@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Wozniak, Chris <wozniak.chris@epa.gov>; Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>; Segal, Mark <Segal.Mark@epa.gov>; Sid Abel <Sidney.W.Abel@aphis.usda.gov>

Subject: RE: NASEM Report - Future of Biotechnology Compiled ERRATA comments

I made the changes requested by Ritu regarding the comments that were attributed to FDA but should be attributed to USDA. Regarding the public participation we are fine to have it attributed solely to USDA. Carolina, I also think you did an excellent job in pulling this together quickly and effectively. Many thanks,. Neil

From: Nalubola, Ritu [<mailto:Ritu.Nalubola@fda.hhs.gov>]

Sent: Wednesday, March 29, 2017 7:16 AM

To: Penalva-Arana, Carolina <Penalva-Arana.Carolina@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Wozniak, Chris <wozniak.chris@epa.gov>; Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>; Segal, Mark <Segal.Mark@epa.gov>; Hoffman, Neil E - APHIS <Neil.E.Hoffman@aphis.usda.gov>; Abel, Sidney W - APHIS <Sidney.W.Abel@aphis.usda.gov>

Subject: RE: NASEM Report - Future of Biotechnology Compiled ERRATA comments

Hi Carolina – Thanks for pulling this together so nicely.

I've added my edits in attached. In a couple of places where you listed items as FDA comment, I think those are from USDA but you'll have to double check and fix – I flagged those for you.

I also flagged one item re: Oxitec mosquito for EPA, and responded to USDA's comment about public participation.

I'm available for any further back-forth. I'll keep an eye on bb and can log in, as needed, later today.

Thanks!

Ritu

From: Penalva-Arana, Carolina [<mailto:Penalva-Arana.Carolina@epa.gov>]

Sent: Wednesday, March 29, 2017 5:24 AM

To: Nalubola, Ritu; Mendelsohn, Mike; Wozniak, Chris; Milewski, Elizabeth; Segal, Mark; Hoffman, Neil E - APHIS; Sid Abel

Subject: NASEM Report - Future of Biotechnology Compiled ERRATA comments

Hello everyone.

Attached is a copy of the compiled comments/suggestions for corrections in the report. It is only being mailed to the immediate drafting group (if I missed someone and/or you wish to share it with others feel free).

As agreed they are compiled in page order. I divided them into columns and tried to emphasize the suggestions (and changes when possible).

I only have one specific question that FDA and EPA needs to consider based on a comment from USDA on public consultation, and I highlighted it, so you can easily find it.

I am in Paris thru Friday and thus 6 hours ahead. If possible I will work on any comments received late today; otherwise everyone will have a final copy by Friday. I will let Bryan know we will get the comments to him by Friday.

All the best.

Carolina Penalva-Arana

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